

**NEGOTIATED RULEMAKING COMMITTEE FOR
THE SHARED RISK EXCEPTION**

MINUTES¹

Organizational Meeting

June 17-18, 1997

Washington, D.C.

On June 17 through 18, the Department of Health and Human Services (HHS), Office of the Inspector General (OIG), held an organizational meeting with Members of the Negotiated Rulemaking Committee for the Shared Risk Exception. (See **Attachment A** for a list of appointed Committee Members and alternates who attended the meeting.) The purpose of the meeting was to discuss proposed organizational groundrules, to hear presentations relevant to the rulemaking, and to discuss the process for future meetings.

The organizational meeting was noticed in the Federal Register and was open to the public. The meeting was held at the Holiday Inn Capitol, Washington, D.C.

FIRST DAY, JUNE 17, 1997

Introductions:

After welcoming remarks by June Gibbs Brown, the HHS Inspector General, the Committee Members introduced themselves and others accompanying them. The facilitators -- Judy Ballard, Doris Campos-Infantino, and Chris McNickle -- then introduced themselves, explained how they see their role, and reviewed the meeting agenda.

Proposed Organizational Groundrules:

A discussion of the organizational groundrules, drafted and proposed by the facilitators based on groundrules of similar committees, focused on the following:

- Concerns about the second sentence of proposed groundrule 7.a., regarding use of statements by Committee Members -- specifically, whether this provision was necessary to permit Committee Members to discuss openly and freely what types of managed care arrangements are being developed, or, on the

¹ These minutes were prepared by the facilitators for the convenience of the Committee Members and should not be construed to represent the official position of the Committee or of any Member on what transpired at the meeting.

other hand, whether the provision might be used to try to immunize illegal arrangements from prosecution;

- Concerns about proposed groundrule 3.c., permitting HHS to discontinue negotiations at any time;
- The definition of "consensus" in proposed groundrule 3.a., including possible risks and benefits of requiring unanimous concurrence and what it means to say a Committee Member can "live with" a proposal;
- Concerns that Committee Members may not be able to "ensure" that any consensus is acceptable to all of their constituents, as provided in proposed groundrule 2.e.(5);
- Questions about proposed groundrules 4.d. and e.-- specifically, whether the Committee should have any opportunity for input on comments to an Interim Final Rule developed by the Committee and whether HHS/OIG would explain any differences between the Committee consensus and any published rule;
- Concerns that Committee Members provide information material to the negotiations in a timely way; and
- Concerns about whether Committee Members could provide information about the negotiations to their constituents through association newsletters or answer press inquiries if they agreed to proposed groundrule 7.c.

The discussion resulted in the Committee adopting without objection some provisions as proposed, tabling proposed groundrules 7.a. and 3.c., deleting proposed groundrule 7.c., and adopting without objection the following revised provisions:

- 2.e.(1): Each Committee Member agrees to make a good faith effort to attend every session of the Negotiating Committee and provide information that is material to the negotiation in a timely way.
- 2.e.(5): Committee Members are participating in a representative capacity. They are expected to consult during the negotiations with their constituents, and seek to ensure that their constituents can live with any agreement developed by the Committee.

- 4.d.: After the close of the comment period on the Notice of Interim Final Rulemaking, the facilitator will consult with the Committee to determine whether the Negotiating Committee will reconvene to consider the comments before the final rule is circulated for review and approval within the appropriate Federal agencies.
- 4.e.: Except for the appropriate Federal agencies, each party that signs the written statement agrees not to take any action to inhibit the adoption of the Interim Final Regulations as final regulations to the extent the final regulations and their preamble have the same substance and effect as the written statement. In the preamble, the appropriate Federal agencies will note, and explain the rationale for, any differences between the final regulation and the written statement.²
- 6.a.: The negotiations will be conducted under the Federal Advisory Committee Act (FACA) and the Negotiated Rulemaking Act of 1990 and the provisions of Section 216 of the Health Insurance Portability and Accountability Act of 1996.

Presentations:

After a lunch break, the Committee heard the following presentations:

- Tracy Jensen, Legislative Liaison for the Office of Managed Care of the Health Care Financing Administration (HCFA), explained about Medicare contracting, on either a risk or cost basis, with "eligible organizations" under section 1876 of the Social Security Act and about other Medicare managed care arrangements, such as health care prepayment plans providing Part B benefits under section 1833 of the Act. She also spoke about pending legislation that would allow HCFA to contract with Provider Sponsored Organizations (PSOs).

² Facilitators' note: the underlined phrase "to the extent the final regulations" was inadvertently omitted from the version given to Committee Members at the end of the meeting, but was in the substitute provision proposed by the OIG.

- Lee Partridge, a Committee Member representing the National Association of State Medicaid Directors, spoke about managed care in State Medicaid programs and the shift to a diversity of risk-based arrangements under Medicaid waivers.
- Scott Nelson, Senior Program Analyst for the Department of Defense (DOD) and its representative for the negotiated rulemaking, explained about DOD's Tri-Care program and how DOD shares gains and losses with its regional contractors in that program.
- Mark Joffe, counsel to the American Association of Health Plans, gave an overview of organizations that might be involved in risk-sharing arrangements, illustrating how complicated those arrangements might be.
- James Blumstein, Professor at the Vanderbilt Law School, gave his perspective on the movement in health care from a "professional paradigm," reflected in the history of the anti-kickback provisions, to a "market paradigm," and on the results of applying anti-kickback provisions in a managed care context, particularly with the possibility of "whistleblower" suits under the False Claims Act.
- D. McCarty Thornton, Committee Member representing HHS/OIG, gave his perspective on the anti-kickback provisions, the statutory exceptions, and the regulatory "safe harbors." He explained the approach behind those safe harbors: looking for either sufficient financial incentives to control utilization or regulatory oversight, asking what a clever crook could do to slip in, and rejecting general criteria as too subjective.
- Kevin McAnaney, Chief, Industry Guidance Branch, Office of the Counsel, HHS/OIG, discussed more in depth the regulatory safe harbors that affect managed care arrangements, including Medicare risk and cost-based contracts under section 1876 of the Social Security Act and Medicaid contracts under section 1903(m) of the Act. He indicated that the types of risk-sharing arrangements that are potentially subject to anti-kickback provisions, but not within the regulatory safe harbors, may primarily be in employer health plans serving Medicare beneficiaries.

After each presentation, the Committee Members had an opportunity to comment and/or ask questions. As a result of the discussion following the anti-kickback presentations, the OIG representative indicated that the basic theory of the statutory exception makes sense, that in his view "downstream" arrangements under a Medicare risk contract are protected by an existing safe harbor since they cannot result in increased program costs, and that it would be a worthwhile task to come up with protection for bona fide bonus or withhold pools. The OIG indicated, however, that where bonuses or withholds are tied to a utilization target, the OIG would have to ensure that the target would not be manipulated.

Discussion of Committee process:

The Committee then discussed what its process would be for the negotiations. The facilitators proposed a process for identifying issues and interests (needs and concerns). Using the definitions of issues and interests on a sheet provided by the facilitators (**Attachment B** to the minutes), each Committee Member would consult with constituents to develop a list of issues and interests that would be submitted to the facilitators **by July 14, 1997**. The facilitators would then group the issues, if possible, and send compilations of the identified issues and interests to Committee Members as a basis for discussion at the July meeting. The facilitators explained that, although the Convening Report had contained summaries of issues identified during convening interviews, the proposed additional process would permit the Committee Members to state the issues in their own way, to modify the issues based on additional information or changing circumstances, to understand who is raising what issues, and to learn what the other parties' needs and concerns are that should be taken into account in proposing options.

Committee Members raised questions about who would prepare drafts for Committee discussion, when this could be done, and whether the Committee should use workgroups. The facilitators explained that this would depend on what issues are identified, how the Committee groups issues for discussion, and who is affected by each group of issues.

Various suggestions were made about how to expedite the negotiations, including the following: that the actual language of the anti-kickback exception that is the subject of the negotiations should first be parsed line by line; that the Committee use case studies as a basis for discussing issues; that the Committee form some sort

of steering committee (either to come up with meeting agendas and process or to play a more substantive role); and that concerns/issues be introduced sporadically, including questions that are stimulated by the presentations.

The meeting was adjourned for the day at about 5:00.

SECOND DAY, JUNE 18, 1997

The Committee reconvened at about 9:00 a.m. on June 18, 1997.

Additional Presentations:

The following presentations were made in the morning:

- Kathy Kenyon of Davis, Wright, Tremaine, which advises the American Medical Group Association, described common health plan approaches to risk-sharing arrangements, under which the health plan shifts maximum risk, shifts minimum risk, or shares risk. She also gave examples of common approaches to "downstream" risk-sharing.
- Kirsten Hopper, Member of the Board of Directors of The IPA Association of America, then provided some specific examples of types of incentive arrangements between an IPA and physician members.
- Robert Leibenluft, Assistant Director for Health Care, Federal Trade Commission (FTC) Bureau of Competition, spoke about the 1996 Statements of Antitrust Enforcement Policy in Health Care issued by the FTC and the Department of Justice. He explained the concepts of "risk-sharing" and "substantial financial risk" as used in that policy statement, the context in which "substantial financial risk" is used for antitrust purposes, and considerations that he thinks are important for the Committee to keep in mind.
- Tony Hausner, Senior Analyst, HCFA, spoke on the physician incentive plan rule, the definition of "substantial financial risk for purposes of that rule, the requirements that an incentive arrangement must meet when "substantial financial risk" is assumed -- stop-loss insurance and beneficiary surveys, and the exception for arrangements with more than 25,000 lives.

- Joanne Sinsheimer, also of HCFA, gave her perspective on the physician self-referral (Stark) law, how managed care is taken into account in the implementing rules, and the difficulties of applying Stark to Employer Group Health Plans and to a Management Services Organization (MSO) where the physician has an ownership interest in the MSO and the MSO has an ownership interest in the group practice.

After each presentation, Committee Members commented and/or asked questions. One Member wanted clarification of bonus incentives for meeting quality of care measures, including how many total bonus points a physician must generally have to receive a bonus. Questions were raised about the effect of giving an IPA Board discretion about whether to award bonuses. Discussion also addressed the differences between how "substantial financial risk" is used in physician incentive rules and in the antitrust policy statement. Several Committee Members expressed the opinion that the antitrust policy statement is more comparable to the shared-risk exception than the physician incentive plan rule.

After a lunch break, the following presentations were made:

- Sanford Teplitzky, who is with Ober, Kaler, Grimes and Shriver and an alternate representative for the American Health Care Association, explained how long-term care fits into the spectrum of managed care services, how the long-term care industry is providing more subacute care on one hand and more home-based services on the other, and why the shared-risk exception is important to the long-term care providers.
- Yvonne Bice, Committee Member representing the National Association of Community Health Centers, described some of the requirements Community Health Centers are subject to as federal grantees, ways in which Community Health Centers are moving into managed care arrangements, and special problems that they face in doing so.
- Michael Weiden, Committee Member representing the National Rural Health Association, described some of the problems rural areas face in developing managed care arrangements, the difference in evaluating risk for a rural area with limited numbers of patients and providers, and the concern that a rule developed

by the Committee not have unintended consequences for rural areas.

Continued Discussion of Groundrules:

Law enforcement representatives offered the following substitute to proposed groundrule 7.a.:

All parties agree to act in good faith in all aspects of these negotiations. Committee Members are not under any obligation to identify the parties to an arrangement under discussion, to state whether the arrangement in fact exists, or to refer to it in any way other than in hypothetical terms. Committee Members are encouraged to describe arrangements in generic terms. It is the intent of the Committee that other attendees at the Committee's meetings would also voluntarily comply with this provision in order to support the regulatory negotiation process by encouraging free and open exchange of ideas, views, and information. Personal attacks and prejudiced statements will not be tolerated.

No Committee Member present indicated an objection to adopting this substitute provision.

The Committee also took up proposed groundrule 3.c., which had been tabled at the request of a Committee Member who wished to review what the Negotiated Rulemaking Act provided regarding agency termination of a committee. The Committee reviewed an addition to the provision that had previously been proposed. No Committee Member present indicated an objection to adopting this groundrule, revised as follows:

The Committee or the Department of Health and Human Services may discontinue the negotiations at any time.

In the event the Secretary proposes to discontinue the negotiations, the Committee Members will be given information in advance as to the reasons why and a reasonable opportunity to comment.

Since some Committee Members had been absent at various times during the meeting without having an alternate present, the facilitators asked whether the Committee wished to discuss what would constitute a quorum for purposes of a Committee meeting. This led to a discussion of whether Committee Members had to designate one single alternate or could have others substitute for them as necessary, whether a Member could give a proxy to

another Member when unable to be present, and whether, if the Committee agreed that consensus meant unanimous concurrence of those present, a Member who was not present could reopen the matter and, if so, on what conditions. Some Committee Members expressed concerns over their ability to have an alternate present at all times and over being excluded from a vote, without notice, if they had an unforeseen conflict. Others expressed concerns over having to revisit issues that had already been decided. One Committee Member indicated that she would never concur in reopening an issue solely on the basis that a Committee Member was not present when a vote was taken. The facilitators expressed the following concerns, based on their experience with consensus-building processes:

- If a Member votes by proxy against an option being considered but is not there to explain the reasons why the option is not acceptable, it would be difficult for the Committee to know how to craft a new option to meet that Member's concerns and negotiations would be delayed.
- Substituting alternates who have not been involved in the Committee's previous work may be disruptive.
- If preliminary consensus is reached on some matters with concurrence only of Members who are present, there may be difficulty with getting a Member who was not present at the time to sign a Committee agreement at the end of negotiations.

The facilitators also explained, in response to a question, that whether the Committee might want to reach consensus on intermediate matters might depend on how the issues are grouped and interrelated. As a result of the discussion, the Committee Members present drafted changes to proposed groundrule 3.a. defining consensus, so that it now reads:

The Committee will operate by consensus. Committee decisions will be made with unanimous concurrence of all Committee Members present when there is a quorum. A quorum is two-thirds of Committee Members. Concurrence means only that the Committee Member can live with the decision being considered by the Committee.

No Member present objected to adopting this provision as revised.

The Language of the Exception:

The Committee then focused on the language of the shared-risk exception, to begin to identify areas of agreement or disagreement and some issues which might arise in defining statutory terms. The statutory exception reads:

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.

There was some discussion about whether the implementing rule would need to define the term "remuneration." One Member pointed to a definition of "remuneration" in the Health Insurance Portability and Accountability Act. Others said that "remuneration" was effectively defined in the anti-kickback provisions by the language referring to "remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" and the listing of types of remuneration to which the provisions do not apply. The result of this discussion was concurrence that--

- the shared-risk exception itself carves out remuneration that is not remuneration for purposes of anti-kickback liability; and
- the rule does not need to define "remuneration" separately.

The Committee also discussed whether it would need to define "organization." While there was acknowledgment that the term "eligible organization" is defined in section 1876 of the Social Security Act, a question was raised about whether the Act contained a definition of "organization" that would apply. In response to a question by a Committee Member about whether the term "organization" should be limited to health maintenance organizations, no one indicated that such a limit would apply. Some Committee Members did indicate, however, that it is a "live issue" whether the term "organization" should be defined in the rule. There was also some discussion of the scope of the existing safe harbors.

One member asked for clarification of whether the safe harbor for Medicaid managed care applies when section 1903(m) of the Social Security Act is waived.

The facilitator noted that input during convening appeared to indicate that there was no dispute that the exception contained two parts: 1) remuneration pursuant to a written agreement between an eligible organization under section 1876 and an individual or entity providing items or services or a combination thereof; and 2) remuneration pursuant to a written agreement between an organization and an individual or entity providing items or services, or a combination thereof, if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide. No one indicated that they disputed this.

Some Committee Members said that the first part of the exception was self-defining. Others disagreed, identifying the following issues:

- Does the first part of the exception apply to "downstream" arrangements?
- What is meant by "or a combination thereof"?
- What is the scope of "items or services" -- Is it just those pursuant to a § 1876 contract?
- What is a "written agreement"? -- For example, does it have to be for a term of time; what are the payments based on; what about services not listed in the agreement?

It was also mentioned that the pending PSO legislation may change the scope of this part of the exception.

With respect to the second part of the exception, the following issues were identified:

- What is a "risk-sharing arrangement"?
- What is "substantial financial risk"?
- What are items or services that the individual or entity is "obligated to provide"? - Is it only the benefit package or also the administrative side?
- Is the risk business risk or insurance risk?

The facilitators then answered some questions about the process of generating written issues/interests lists.

Agenda for the Next Meeting:

The following items were put on the agenda for the next meeting, planned for **July 28-30**, 1997 at the Holiday Inn Capitol:

- Presentation by Mark Joffe: How employer plans interface with Medicare and Medicaid
- Presentation by the National Association of Insurance Commissioners: Risk for purposes of state regulation of the business of insurance
- Presentation or Materials: Medicare demonstrations with risk-sharing
- Groundrules
- Discussion of Issues/Interests/Options
- Discussion of how to address the issues and interests - what process to use (for example, workgroups)?

The following information will be provided at the next meeting:

- HCFA will provide its Contractor Manual and Compliance and Monitoring Guide.
- The OIG will provide outlines of the managed care safe harbors.
- The OIG will provide information about whether there is a definition of "organization" that applies.

The Committee also discussed when and where meetings would be held after July. The OIG indicated that August was not feasible and that the OIG was having difficulty obtaining hotel space for September, but was looking at space available the end of September. Some Members indicated a conflict then, so the OIG asked Members to indicate dates on which they had a conflict in September, either before leaving the meeting or as soon as possible by telephoning **Joel Schaer at 202-619-0089**.

In response to a question about why a federal facility could not be used, the facilitators explained the difficulties with scheduling a public meeting in a secure

facility. Several members indicated that they had suitable space that might be available if they had enough advance notice, and were asked to provide information to Joel Schaer about this. Members indicated they saw no problem in using space offered by another Committee Member.

An opportunity was provided for the public to make oral statements to the Committee. None was offered.

The meeting was adjourned at about 4:45 p.m.

ATTACHMENT A - LIST OF PARTICIPANTS

Committee Members present for part or all of the meeting:

Candace Schaller, American Association of Health Plans
 Cheryl Matheis, American Association of Retired Persons
 Ken Burgess, American Health Care Association
 Mary R. Grealy, American Hospital Association
 Edward B. Hirshfeld, American Medical Association
 Brent Miller, American Medical Group Association
 Susan E. Nestor, BlueCross BlueShield Association
 Charles P. Sabatino, Consumer Coalition for Quality
 Health Care
 Missy Shaffer, Coordinated Care Coalition
 Laura Steeves Gogal, Federation of American Health
 Systems
 Eddie Allen, Health Industry Manufacturers Association
 Kylanne Green, Health Insurance Association of America
 Donald C. Brain, Jr., Independent Insurance Agents of
 America/National Association of Health Underwriters/
 National Association of Life Underwriters
 S. Lawrence Kocot, National Association of Chain Drug
 Stores
 Yvonne Bice, National Association of Community Health
 Centers
 Stephen M. Spahr, National Association of Medicaid Fraud
 Control Units
 Lee Partridge, National Association of State Medicaid
 Directors
 Michael Weiden, National Rural Health Association
 Russel A. Bantham, Pharmaceutical Research and
 Manufacturers of America
 J. Mark Waxman, The IPA Association of America
 Karen A. Morrisette, Department of Justice
 D. McCarty Thornton, Department of Health and Human
 Services Office of the Inspector General

Alternate substituting for Committee Member:

Stephanie Lewis, National Association of Insurance
 Commissioners

Alternates identified and/or substituting for Committee
 Member for part of the meeting:

Michelle Fried, AAHP; Sandy Teplitzky, AHCA; Kathy Nino,
 AMA; Mary L. Koffner, AMGA; Julie Simon Miller, BCBSA;
 Brian Lindberg, CCQHC; Jonathon M. Topodas, CCC; Justine
 Germann, HIMA; Jane Galvin and Kathleen H. Fyffe, HIAA;
 Janet Stokes, NAHU; Freda Mitchum, NACHC; Barbara Zelner,
 NAMFCU; Jennifer Goodman, NASMD; Marjorie Powell, PhARMA;
 Paul Cooney, TIPAAA; Kevin McAnaney, HHS/OIG.